

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**IN RE: ABBOTT LABORATORIES, ET
AL., PRETERM INFANT NUTRITION
PRODUCTS LIABILITY LITIGATION**

MDL No. 3026

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This Document Relates to:

ALL CASES

Hon. Rebecca R. Pallmeyer

JURY DEMAND

**DEFENDANTS' MOTION TO EXCLUDE
PLAINTIFFS' EXPERT DR. JENNIFER SUCRE**

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INTRODUCTION

This litigation pits Plaintiffs against the scientific consensus. As the FDA, CDC, and NIH explained in a “Consensus Statement” last fall, “[t]here is no conclusive evidence that preterm infant formula causes NEC” (necrotizing enterocolitis), and “it is the absence of human milk—rather than the exposure to formula—that is associated with an increase in the risk of NEC.” Ex. 1. Behind this consensus are thousands of studies on NEC and long clinical experience with preterm infant formula, which has been on the market for more than forty years.

To overcome this consensus, Plaintiffs have engaged the services of Dr. Jennifer Sucre, a neonatologist who focuses on lung development and who has never researched or published on NEC, has never published on infant formula or its components, and has certainly never published any statement claiming that formula causes NEC. But now, Dr. Sucre claims to have discovered that formula affirmatively causes NEC in preterm infants. Indeed, she says that she has discovered—from a review of public literature, after being retained by Plaintiffs’ counsel—that *all* the macronutrients in formula (fat, proteins, and carbohydrates) cause NEC in several ways.

Dr. Sucre is Plaintiffs’ only expert who will claim to know how formula causes NEC. But her opinion is fatally flawed. To start, it relies on the analysis of Plaintiff’s epidemiologist, Dr. Logan Spector—so if his opinion is excluded (as it should be), then hers must be too.

Dr. Sucre’s opinion is also unreliable for other reasons that routinely result in exclusion. First, her theories (which, again, she has never published) have not been generally accepted by the scientific community. Indeed, they are “unique and isolated to this litigation.” *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1234 (S.D. Fla. 2022). Dr. Sucre “stand[s] alone with [her] opinion[], bereft of support from the scientific community at large.” *Id.* at 1188. Second, Dr. Sucre bases her mechanism theories entirely on studies in rodents, pigs, and Petri dishes, while ignoring studies involving actual humans. For instance, she relies on

animal studies to claim that the components in formula are malabsorbed but ignores human data showing that they are not. This “cherry picking highlights the analytical gap between [her] methodology and conclusion” and requires exclusion. *Cates v. Whirlpool Corp.*, 2017 WL 1862640, at *15 (N.D. Ill.) (St. Eve, J.). Third, Dr. Sucre has no opinion on what level of exposure to formula is required to cause NEC. This defect is fatal; a causation expert must show that “the dose to which the plaintiff was exposed is sufficient to cause the disease.” *Wintz v. Northrop Corp.*, 110 F.3d 508, 513 (7th Cir. 1997).

Finally, in addition to being unreliable, Dr. Sucre’s opinion is unhelpful and should be excluded for that reason too. Dr. Sucre admits that it is impossible to know which, if any, of her proposed mechanisms caused NEC in any one infant—such as RaiLee Mar in the first scheduled bellwether trial. Worse, she testified that it is **impossible** to know whether formula caused an infant’s NEC—or whether, instead, the infant developed NEC because he or she lacked sufficient protection provided by human milk. In other words, Dr. Sucre intends to provide the jury with theories that—by her own admission—nobody would have any basis to conclude caused NEC in any specific infant. Such testimony is unhelpful to a jury charged with determining whether Dr. Sucre’s theories explain the cause of NEC in these specific cases.

BACKGROUND

Dr. Sucre is a neonatologist at Vanderbilt University School of Medicine. *See* Ex. 2 (CV) at 2. Her “research focuses on lung development.” Ex. 3 (Sucre Dep.) at 18:17–19. The words “NEC” and “necrotizing enterocolitis” appear nowhere on her CV, and she has never been asked to speak about NEC at a conference. *Id.* at 20:19–22, 21:2–6. That is no surprise. She has “never published” any peer-reviewed paper on NEC, much less on NEC’s “pathophysiology” or “mechanism of action”—the subject of her testimony here. *Id.* at 19:3–24. She admits she has “never conducted” animal or *in vitro* research (a study performed on cells in a lab, outside a

living organism) on NEC. *Id.* at 19:25–20:7. And she has “never received any funding” to research NEC “outside this litigation.” *Id.* at 20:14–17.

Nor has Dr. Sucre ever “published a paper” about “preterm infant formula,” its “components,” or preterm infants’ ability to digest and absorb it. *Id.* at 35:7–37:15. And she has “never written in a peer-reviewed publication” that preterm infant formula or its components can “cause[],” “contribute[] to,” or “increase[] the risk of NEC.” *Id.* at 21:25–22:11, 27:20–29:6. In fact, Dr. Sucre agrees that formula is “a critically important option for premature infants” when “there is no human milk available” (*id.* at 104:12–17); that it is “part of the standard of care” when no human milk is available (*id.* at 107:16–21); that she has personally “ordered that preterm infant formula be fed to premature infants” (*id.* at 360:8–11); that her hospital “uses preterm infant formula in its NICU to this day” (*id.* at 361:4–8); that “[t]he majority of premature infants that are fed formula do not end up getting NEC” (*id.* at 361:10–13); and that infants can develop NEC “without ever having been fed formula” (*id.* at 361:22–24).

Despite all this, Dr. Sucre now opines—in the context of this litigation—that formula “is causally associated with and/or substantially contributes to the development of NEC.” Ex. 4 (Second Am. Disclosure) at 40. She testified that this causation opinion rests on “two parts”—“epidemiologic data” and “biological plausibility.” Ex. 3 at 336:2–16. For the epidemiology piece of it, she “deferred” to Plaintiffs’ epidemiology expert, conducting no “independent analysis of epidemiologic data” herself. *Id.* at 344:2–8, 346:7–14. Dr. Sucre supplies the “biological plausibility” piece. In her opinion, the “carbohydrates, proteins, and fats contained in cow’s milk-based formula cause or substantially contribute to NEC.” *Id.* at 576:21–577:4; *see also* Ex. 4 at 36 (“undigested [formula], in the form of carbohydrates, proteins, and fats, result[s] in malabsorption of the CMBF in the intestine . . .”). She says ***all*** these macronutrients directly

or indirectly activate a cell receptor called TLR4, which triggers an inflammatory process that leads to NEC, in four ways: (1) these nutrients directly activate TLR4; (2) these nutrients are cytotoxic, which means they damage intestinal cells directly, and those damaged cells then activate TLR4; (3) these nutrients are malabsorbed, causing pathogenic bacteria to proliferate, which then activate TLR4; and (4) the bacteria that feed on the malabsorbed nutrients cause overdistension of the gut, which activates TLR4. *See id.* at 24, 37–39.

Other than paid plaintiff experts in formula litigation—who have never published their theories and who, in fact, still use formula—nobody has concluded that formula causes NEC. No surprise, then, that behind Dr. Sucre’s dubious opinion is a dubious methodology. She searched PubMed (a medical literature database) for articles with the terms “Necrotizing Enterocolitis” and “Formula” published between 2014 and 2024, finding 545 results. Ex. 4 at 8. She then considered “additional manuscripts,” no matter when they were published (*id.* at 8–9), such as the only paper she cites (a 2012 *in vitro* study) in support of her theory that formula fat is cytotoxic (Ex. 3 at 253:14–254:7, 257:3–258:19, 261:18–262:4). But her method—including her ten-year timeframe, her evaluation of studies within that timeframe, and her handpicked selection of studies outside that timeframe—excluded critical data. For example, she ignored human studies that are directly relevant to her theories, that satisfied her search criteria, and that were cited in materials in her search. Indeed, she admitted that no human data supports her theories:

Q. And you don’t have any peer-reviewed study in humans showing that premature infants mal-absorb or mal-digest bovine protein, correct?

A. No. [*Id.* at 141:2–7 (form objection omitted).]

See also id. at 140:20–25 (same for carbohydrates), 241:9–14 (same for fat), 527:18–22 (no human data shows formula carbohydrates are cytotoxic), 403:21–25 (same for protein), 262:23–263:4 (same for fat). To be clear, as discussed below, there is no shortage of relevant human

data; Dr. Sucre just failed to identify or consider it. She instead relied entirely on animal and *in vitro* studies:

Q. Every study that you cited in support of your theory that formula or the components in formula trigger TLR4 is either an *in vitro* study or an animal study, correct?

A. That's correct. [*Id.* at 329:4–8.]

Dr. Sucre performed no “analysis on the amount of exposure to formula” or any of its components “that is necessary to contribute [to] or cause NEC in preterm infants,” and she does not know “how long it takes”—“hours, days, or weeks.” *Id.* at 90:21–25, 120:8–12, 434:14–25. Nor does she “propose an alternative formulation.” *Id.* at 37:16–22. She also says there is no way to determine what component of formula, if any, caused NEC in any specific case. *Id.* at 133:4–17. In fact, she testified that determining whether an infant’s NEC was caused by any component of formula—or, rather, “due to the lack of getting the protection of mother’s own milk”—is “not something that is able to be determined for an individual.” *Id.* at 135:16–136:2.

ARGUMENT

I. Dr. Sucre’s opinion relies on Dr. Spector’s opinion—and if his opinion is excluded, then hers must be too.

Dr. Sucre recognizes that animal and Petri-dish data is not enough to support her causation opinion. *See* Ex. 3 at 336:2–342:11 (Q. “Are you comfortable concluding that preterm infant formula causes NEC in humans solely based on the *in vitro* [and] animal data, yes or no? A. I don’t think I can answer the question.”). So she claims to rely on “epidemiologic data” too. *Id.* at 336:2–16, 444:8–16; Ex. 4 at 15–16. But she did not conduct any “independent analysis of epidemiologic data” (Ex. 3 at 346:7–14), deferring entirely to Plaintiffs’ epidemiologist, Dr. Spector (who relied, in turn, on biostatistician Dr. Rebecca Betensky) (*id.* at 344:2–8).

There is no way to disentangle Dr. Sucre’s causation opinion from Dr. Spector’s opinion, and her biological mechanism theories cannot stand on their own to support her opinion that formula causes NEC. After all, “[b]iological plausibility . . . is only a subsidiary consideration in the larger question of general causation.” *In re Viagra (Sildenafil Citrate) & Cialis (Tadalafil) Prod. Liab. Litig.*, 424 F. Supp. 3d 781, 791 (N.D. Cal. 2020). As a result, if Dr. Spector’s opinion is excluded, then Dr. Sucre’s opinion must be excluded as well.¹

II. Dr. Sucre’s opinion should be excluded because her methodology is unreliable.

Dr. Sucre’s opinion should also be excluded because it is not “the product of reliable principles and methods.” Fed. R. Evid. 702(c). First, her theories fall far outside the scientific consensus and are isolated to this litigation. Second, she cherry-picks data and ignores powerful evidence from human studies undermining her conclusions. And third, she cannot say how much formula is necessary to cause NEC—a critical step in proving causation.

A. Dr. Sucre’s theories are not generally accepted in the scientific community.

In considering an expert’s “general causation conclusions,” courts consider whether they find “widespread acceptance amongst independent scientists” or are, instead, “unique and isolated to th[e] litigation.” *In re Zantac*, 644 F. Supp. 3d at 1193, 1234; *see also Robinson v. Davol Inc.*, 913 F.3d 690, 695 (7th Cir. 2019) (court should evaluate “whether the expert’s theory has been . . . generally accepted within the specific scientific field” (citation omitted)). This “can be an important factor in ruling particular evidence admissible.” *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594 (1993). “When an expert’s theory lacks any acceptance, let alone general acceptance, in the scientific community[,] it is an indication of an unreliable

¹ Any independent opinion that Dr. Sucre might offer about the epidemiological literature would be undisclosed, as well as unreliable. *See In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2015 WL 3669933, at *25 (N.D. Ill.) (Pallmeyer, J.) (excluding expert who “has not sufficiently explained . . . what reasoning, principles, or methodology he applied”).

methodology.” *In re Zantac*, 644 F. Supp. 3d at 1234 (quotations omitted). Thus, the Advisory Committee Notes to Rule 702 instruct that when an expert “reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied.”

“The Seventh Circuit and courts around the country” therefore “view such scientific isolation as an evidentiary red flag.” *In re Paraquat Prods. Liab. Litig.*, 730 F. Supp. 3d 793, 850 (S.D. Ill. 2024). Take *In re Zantac*, where the court excluded plaintiff experts who opined that the chemical ranitidine causes cancer; central to the court’s conclusion was the “lack of independent scientific support” for that opinion. 644 F. Supp. 3d at 1191. “[T]here is no published study or governmental finding that agrees with the Plaintiffs’ experts,” emphasized the court; “there is no published conclusion or finding, outside of this litigation, that concludes that ranitidine causes cancer of any kind.” *Id.* Similarly, in a case excluding experts who opined that prenatal acetaminophen use causes ADHD, the court emphasized the position of the FDA and medical organizations that acetaminophen was safe and that evidence of causation was lacking.

In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., 707 F. Supp. 3d 309 (S.D.N.Y. 2023). The court found “no generally accepted scientific conclusion that in utero exposure to acetaminophen causes” ADHD, “and major medical organizations and regulators cautioned against drawing causal inferences from the existing body of scientific literature.” *Id.* at 333–34.

So too here. Dr. Sucre’s “theory has not been adopted or independently validated in *any* peer-reviewed scientific analysis outside of this litigation.” *In re Paraquat*, 730 F. Supp. 3d at 850. “[N]o independent scientist or governmental body has made the analytical leap from the existing data” that Dr. Sucre has made. *In re Zantac*, 644 F. Supp. 3d at 1234. She “stand[s] alone with [her] opinion[], bereft of support from the scientific community at large.” *Id.* at 1188.

Even Plaintiff's other causation experts cannot identify anybody else who agrees with Dr. Sucre. Ex. 6 (Spector Dep. excerpt) at 133:11–23; Ex. 15 (DeZure Dep. excerpt) at 183:25–184:8.

What's more, as in *In re Acetaminophen*, “major medical organizations and regulators have cautioned against drawing causal inferences from the existing body of scientific literature.” 707 F. Supp. 3d at 333. On October 3, 2024, the FDA, CDC, and NIH published a “Consensus Statement” with a clear message: “There is no conclusive evidence that preterm infant formula causes NEC.” Ex. 1. It continued, “[a]vailable evidence supports the hypothesis that ***it is the absence of human milk—rather than the exposure to formula***—that is associated with an increase in the risk of NEC.” *Id.* (emphasis added). The Consensus Statement discusses a federally commissioned report on “the scientific evidence regarding enteral feeding practices in premature infants and factors that may protect against or increase risk for NEC.” Ex. 5 at i. That 100-page report, published last September, was prepared by a blue-ribbon panel of experts in NEC and preterm infant nutrition, among other things. *See id.* at 28–30. It considered the latest “scientific research literature on NEC,” sifting through nearly 4,000 papers to identify the 664 “key publications that were most closely related to the relationship between NEC and infant feeding.” *Id.* at 73; *see id.* at 74–91. And it concluded that the “absence of human milk”—***not*** “exposure to formula”—is responsible for an increased risk of NEC. *Id.* at 15.

In sum, Dr. Sucre—who has never before researched or published on NEC—claims to have discovered several mechanisms by which every macronutrient in formula causes NEC based on public literature that she reviewed solely for this litigation while being funded by Plaintiffs’ lawyers. Despite formula’s forty years on the market and the thousands of studies on NEC, nobody outside this litigation has ever drawn this conclusion, and the FDA, CDC, NIH,

and blue-ribbon panel of experts have forcefully rejected it. If this is not “evidence of an unreliable methodology,” nothing is. *In re Zantac*, 644 F. Supp. 3d at 1234.

B. Dr. Sucre cherry-picks favorable data and ignores data that undermines her theories.

It’s no surprise that Dr. Sucre reached conclusions never before reached by anyone, given her flawed methodology. She ran a PubMed search limited to the last ten years, omitting decades of NEC research, then reached outside that period to hand-select studies she determined were helpful to her opinions, and then ignored or failed to identify many human studies that undermine her conclusions. Such a cherry-picked analysis is unreliable, as it is not “based on sufficient facts or data” or “the product of reliable principles and methods.” Fed. R. Evid. 702.

“Cherry-picking is a form of result-driven analysis which undermines principles of the scientific method by applying methodologies (valid or otherwise) in an unreliable fashion.” *In re Acetaminophen*, 707 F. Supp. 3d at 336 (quotations omitted). An expert cannot “pick and choose from the scientific landscape and present the Court with what he believes the final picture looks like.” *In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 563 (S.D.N.Y. 2004) (cleaned up). An expert must evaluate “all of the scientific evidence when making causation determinations.” *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 463 (E.D. Pa. 2014). And when “the expert fails to address evidence that is highly relevant to his or her conclusion,” exclusion “is warranted.” *In re Acetaminophen*, 707 F. Supp. 3d at 336 (citation omitted). In short, “a cherry-picked selection of favorable data” is “unduly results-driven, not good science, and therefore inadmissible.” *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1039 (S.D. Cal. 2021), *aff’d*, 2022 WL 898595 (9th Cir.).

Dr. Sucre picked cherries. Although her literature search was restricted to articles from 2014 to 2024, she freely “evaluated additional manuscripts” from outside that period. Ex. 4 at 8–

9. That would be harmless enough if Dr. Sucre did not simply use the opportunity to hand-select articles that she considered helpful to her opinion. But that's exactly what she did. For example, she relied completely on a 2012 *in vitro* study for her conclusion that formula fat is cytotoxic (and therefore causes NEC). Ex. 3 at 253:14–254:7, 257:3–258:19, 261:18–262:4.

At the same time, in forming her mechanism theories, Dr. Sucre did not account for any literature that undermines them—including randomized controlled trials and other studies reporting human data. *See, e.g., id.* at 175:9–11, 185:14–19, 290:24–291:2. Indeed, while Dr. Sucre sprinkled her reliance list with some epidemiological studies, she focused only on animal and *in vitro* studies and substantively ignored all human studies. *See id.* at 329:4–8. She excluded some of these human studies ostensibly because they were “published before 2014” (*id.* at 181:5–8)—as if nothing published before then could be relevant—but again, that did not stop her from considering earlier publications that she felt *supported* her opinion. The result is that Dr. Sucre ignored important studies like this:

- Shulman 1995 (Ex. 7) was a human study that found that “[p]remature infants do not digest and absorb lactose as well as glucose polymers”—or, in other words, that preterm infants have no issue digesting and absorbing the carbohydrates in formula (a combination of glucose polymers and lactose). This undermines Dr. Sucre’s central theory that “undigested carbohydrates in animal models and preterm humans leads to . . . NEC”—a theory actually based *solely* on “animal models.” Ex. 4 at 26. This highly relevant study was cited in several articles that Dr. Sucre relies on,² but she did not consider it. Ex. 3 at 185:14–19.
- Griffin 1999 (Ex. 10) was a randomized controlled trial that found “no evidence” that increasing the amount of maltose (a carbohydrate in some preterm infant formulas) “altered the incidence of NEC” in preterm infants. *Id.* at 587. Again, this human study undermines Dr. Sucre’s theory and was cited in other papers that she relies on,³ but she does “not recall seeing it.” Ex. 3 at 175:9–11.
- Ng 2019 (Ex. 11) was a review of randomized controlled trials that found “no effect on the risk of necrotising enterocolitis” with intact bovine protein as

² Dr. Sucre relies on Burrin 2020 and Thymann 2009 in her report. *See Ex. 4 at 22, 43, 47.* Both cite Shulman 1995. *See Ex. 8 (Burrin 2020) at 346; Ex. 9 (Thymann 2009) at G1125.*

³ Burrin 2020 cites Griffin 1999. *See Ex. 8 at 346.*

compared to hydrolyzed (broken down) protein. *Id.* at 2. This undermines Dr. Sucre’s theory that bovine proteins cause NEC. She did not consider it, even though it satisfied her search criteria. *See* Ex. 4 at 41–51 (not citing Ng 2019).

- Hellström 2021 (Ex. 12), a randomized controlled trial, found “no significant differences” in NEC risk after supplementing preterm infants with long-chain fatty acids. *Id.* at 362. This study undermines Dr. Sucre’s theory that formula fat causes NEC. It satisfied her search criteria, but she did not consider it. *See* Ex. 4 at 41–51 (not citing Hellström 2021).
- Embleton 2023 (Ex. 13), another randomized controlled trial, found “no significant differences in measures of gut microbial diversity in infants who only received human milk products compared with those receiving bovine milk formula or fortifiers.” *Id.* at 1. “There were no differences in clinical outcomes,” including NEC. *Id.* This study undermines Dr. Sucre’s theory that maldigestion of formula causes bacteria to proliferate, leading to NEC. Dr. Secure did not consider this study (Ex. 3 at 290:24–291:2), even though it satisfied her search criteria and was cited in other literature she reviewed.⁴

Dr. Sucre did not account for any of these human studies, even though they are all directly relevant to her theories. She failed to address human mechanism data at all—even randomized controlled trials, “the gold standard for determining the relationship of an agent to a health outcome.” *Mullins v. Premier Nutrition Corp.*, 178 F. Supp. 3d 867, 882 (N.D. Cal. 2016) (quoting Fed. Jud. Ctr., *Reference Manual on Scientific Evidence* 555 (3d ed. 2011)). Yet human data is known to be more reliable in showing causation than animal and *in vitro* studies. *See, e.g., Wade-Greux v. Whitehall Lab 'ys, Inc.*, 874 F. Supp. 1441, 1483 (D.V.I.), *aff'd*, 46 F.3d 1120 (3d Cir. 1994) (“*In vivo* and *in vitro* animal test data are unreliable predictors of causation in humans.”); *In re Agent Orange Prod. Liab. Litig.*, 611 F. Supp. 1223, 1241 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987) (discussing limitations on animal studies).

The point here is not just that Dr. Sucre missed a few studies or “is substantively wrong” (though she is). *In re Paraquat*, 730 F. Supp. 3d at 850. The point is that she “ignored a voluminous and directly relevant group of scientific studies . . . which dramatically undermine

⁴ Jensen 2024, referenced in Dr. Sucre’s materials, cites Embleton 2023. *See* Ex. 14 at 10.

[her] claim[s]" (*Newton v. Roche Lab'ys, Inc.*, 243 F. Supp. 2d 672, 681 (W.D. Tex. 2002)) and categorically "fail[ed] to consider evidence that did not support her opinion" (*In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213, 261 (S.D.N.Y. 2018), *aff'd*, 982 F.3d 113 (2d Cir. 2020)).

These flaws are fatal. "Ignoring relevant data is not a scientifically valid method." *Cates*, 2017 WL 1862640, at *15. And courts routinely exclude opinions that are "only supported by favorable animal data," including when the expert "fail[s] to reconcile data that does not support her conclusions." *Daniels-Feasel v. Forest Pharms., Inc.*, 2021 WL 4037820, at *15 (S.D.N.Y.), *aff'd*, 2023 WL 4837521 (2d Cir.); *see also In re Onglyza (Saxagliptin) & Kombiglyze XR (Saxagliptin & Metformin) Prods. Liab. Litig.*, 2022 WL 43244, at *17 (E.D. Ky.) (excluding expert who considered only animal data without accounting for contrary human data). Dr. Sucre's willingness to reach outside her search parameters to rely on "helpful" articles—while categorically refusing to consider "unhelpful" human studies—"raises an inference of unreliable application of methodology" and warrants exclusion. *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 797 (3d Cir. 2017).

C. Dr. Sucre cannot say what level of exposure to formula is required to cause NEC.

Dr. Sucre's methodology is also unreliable because she cannot opine on the dose of formula required to cause NEC. "[C]ourts across the country frequently hold that dosage matters with respect to causation." *Mahler v. Vitamin Shoppe Indus., Inc.*, 2023 WL 6141369, at *7 (N.D. Ill.). Indeed, it is a "fundamental principle[] of toxicology" that diseases caused by some exposure "are dose dependent." *Krik v. Exxon Mobil Corp.*, 870 F.3d 669, 675 (7th Cir. 2017). That's why "[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to

sustain the plaintiffs' burden in a toxic tort case." *Allen v. Pa. Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996); *see also In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d 624, 639 (4th Cir. 2018) ("[T]he plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure." (citation omitted)). That's also why a causation expert must "offer an opinion as to whether the dose to which the plaintiff was exposed is sufficient to cause the disease." *Wintz*, 110 F.3d at 513 (citation omitted); *see Krik*, 870 F.3d at 674 (expert must show the plaintiff's "particular dose . . . was a substantial contributing factor to his illness.").⁵

"Ignoring the dose," then, "is a critical error." *C.W. v. Textron, Inc.*, 2014 WL 1047940, at *7 (N.D. Ind.), *aff'd*, 807 F.3d 827 (7th Cir. 2015). And Dr. Sucre ignored dose, no question.

Q. . . . In your work on this case, did you conduct any analysis on the amount of exposure to formula that is necessary to contribute or cause NEC in preterm infants?

A. No. [Ex. 3 at 120:8–12.]

Dr. Sucre thus has "no clue regarding what would be a harmful level of [formula] exposure," so her "testimony does not establish general causation." *Seaman v. Seacor Marine L.L.C.*, 326 F. App'x 721, 726 (5th Cir. 2009); *see also In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 945 (11th Cir. 2024) (affirming exclusion of experts for failure to prove product was "harmful above a particular threshold").

⁵ *See also*, e.g., *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1108 (8th Cir. 1996) (reversing for failure to exclude expert who could not say "what amounts of wood fibers impregnated with formaldehyde involve an appreciable risk of harm"); *Hostetler v. Johnson Controls, Inc.*, 2020 WL 5543081, at *1 (N.D. Ind.) (excluding experts who lacked reliable basis to opine that alleged exposures were toxic at levels plaintiffs experienced); *Grant v. Chemrex, Inc.*, 1997 WL 223071, at *11 (N.D. Ill.) ("[W]ithout scientific facts regarding the exposure level, [an expert] is unable to establish the necessary causal link between the [product] and Plaintiff's injuries.").

Nor can Dr. Sucre evade this requirement by claiming that the level of exposure required to cause NEC is “unknowable.” Ex. 3 at 433:8–22; *see also id.* at 434:14–20 (Q. “[B]ut you can’t tell me . . . how much of those components would be required for it to cause NEC? A. Correct.”). As a legal matter, this claim is no different from an expert’s claim that “each and every exposure” is enough to cause the disease—and both those claims are inadmissible because both would “improperly shift[] the burden to the defendants to disprove causation.” *Krik*, 870 F.3d at 677. If an expert’s “each and every exposure” theory does “not meet the standards required under Federal Rule 702 and *Daubert*” (*id.* at 682), then Dr. Sucre’s “it’s unknowable” theory cannot pass muster either—especially in cases where the infants received *de minimis* amounts of formula. *See* Ex. 15 at 224:20–25 (5% of the infant’s diet in *Mar*); Ex. 16 (Flanigan Rep. excerpt) (less than 10% in *Brown*).

III. Dr. Sucre’s opinion should be excluded because it is unhelpful to the jury.

Independently, Dr. Sucre’s opinion should be excluded because it is unhelpful to the jury. Fed. R. Evid. 702(a). While she opines that formula can cause NEC, she also testified that it is ***impossible*** to determine in any specific case whether formula caused NEC or whether, instead, the infant merely lacked protection from human milk and developed NEC by some other means:

- Q.** Hypothetically, you can’t after the fact look at the baby that had NEC and say this baby got NEC due to something active in formula versus this baby got NEC due to the lack of getting the protection of mother’s own milk. That’s not something you can determine, is it?
- A.** Yeah, that’s – you’re – that’s not – you’re right, that’s not something that is able to be determined for an individual. [Ex. 3 at 135:16–136:2 (objection omitted).]

Similarly, Dr. Sucre testified that “for an actual human baby with NEC,” there is no way to “after the fact . . . isolate which part of the formula caused the NEC.” Ex. 3 at 133:4–17. In other words, Dr. Sucre says that it is impossible to determine (1) whether formula caused NEC in

any one infant and (2) if so, what component in formula was the culprit. To be clear, whether any component in formula caused these infants' NEC is precisely what Plaintiffs need to prove. But by Dr. Sucre's own admission, nobody can prove that. Neither she nor the jury nor anyone else can "link [her] general causation testimony to [these] specific cases." *In re Mentor Corp. Obtape Transobturator Sling Prods. Liab. Litig.*, 2015 WL 7863032, at *1 (M.D. Ga.). Dr. Plaintiff's specific causation expert, Dr. Chandani DeZure, certainly doesn't do it. While she "think[s] there's something in formula that is causing the NEC," she has no idea what it is, deferring to Dr. Sucre "to shed some light on that." Ex. 15 at 109:7–25; *see id.* at 152:15–22. But again, according to Dr. Sucre herself, whether formula caused NEC in any specific infant—and if so, what component is to blame—can never be determined.

As a result, Dr. Sucre's testimony will not "help the trier of fact" decide whether formula caused *these infants'* NEC. Fed. R. Evid. 702(a). "[A] jury should not be asked to speculate on the issue of causation." *Turpin v. Merrell Dow Pharms., Inc.*, 959 F.2d 1349, 1361 (6th Cir. 1992). And expert testimony that asks the jury to speculate is not admissible. *See Cole v. Perry*, 2019 WL 4165304, at *7 (S.D. Ind.) (excluding expert whose testimony "would invite the jury to speculate"); *Bausch & Lomb, Inc. v. Alcon Lab'ys, Inc.*, 79 F. Supp. 2d 252, 255 (W.D.N.Y. 2000) (same).⁶ Dr. Sucre's opinion should be excluded on this basis as well.

CONCLUSION

For all these reasons, this Court should exclude Dr. Sucre's testimony in full.

⁶ This admission independently entitles Abbott to summary judgment because it means the specific-causation inquiry is impermissibly speculative in each case. Abbott refers the Court to (and incorporates by reference) its summary judgment brief on this point.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon counsel of record on January 24, 2025, via the Court's electronic filing system and via email for any material provisionally filed under seal.

/s/ Linda T. Coberly